4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, and 558

[Docket No. FDA-2020-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2020. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2020, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries)

under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During October, November, and December 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 16, 2020	141-536	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	ELURA (capromorelin oral solution)	Dogs and cats	Original approval for management of weight loss in cats with chronic kidney disease	FOI Summary
October 29, 2020	200-692	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161	CYCLAVANCE (cyclosporine oral solution) USP MODIFIED	Dogs	Original approval as a generic copy of NADA 141-218	FOI Summary
November 16, 2020	141-541	QBiotics Group Ltd., suite 3A, level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia	STELFONTA (tigilanol tiglate injection)	Dogs	Original approval for the treatment of non-metastatic cutaneous mast cell tumors and non-metastatic subcutaneous mast cell tumors located at or distal to the elbow or the hock in dogs	FOI Summary
November 25, 2020	200-557	Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211	TZED (tiletamine and zolazepam for injection)	Dogs	Supplemental approval for an intravenous route	FOI Summary
December 14, 2020	141-542	Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., suite 2400, Blacksburg, VA 24060	pPL657 rDNA construct in domestic pigs	Swine	Original approval for an intentional genomic alteration in domestic pigs	FOI Summary
December 16, 2020	200-696	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	SELASPOT (selamectin) Topical Solution	Dogs and cats	Original approval as a generic copy of NADA 141-152	FOI Summary

As provided in the regulatory text, the animal drug regulations are amended to reflect these approval actions. As they are now the sponsor of an approved application, QBiotics Group Ltd. and Revivicor, Inc. will be added to the list of sponsors of approved applications in 21 CFR 510.600(c).

II. Technical Amendments

FDA is making the following amendments to improve the accuracy, consistency, and readability of the animal drug regulations:

- 21 CFR 558.128 is amended to reflect the sponsors of approved conditions of use for chlortetracycline in beef cattle.
- 21 CFR 558.342 is amended to reformat special considerations for labeling and manufacture of melengestrol medicated feeds.
- Typographical errors are being corrected wherever they have been found.

III. Legal Authority

This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities. This rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires *Federal Register* publication of the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug′s sponsor in a "notice, which upon publication shall be effective as a regulation." A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 et seq. See section 512(i) of the FD&C Act; 21 CFR 10.40(e)(3); S. Rep. 90-1308, at 5 (1968).

This document does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a "rule of particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866,

which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 528

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 528, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600:

a. In the table in paragraph (c)(1), add entries for "QBiotics Group Ltd." and "Revivicor, Inc." in alphabetical order; and

b. In the table in paragraph (c)(2), add entries for "086132" and "086134" in numerical order.

The additions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
QBiotics Group Ltd., suite 3A, level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia	086132
* * * * * * *	
Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., suite 2400, Blacksburg, VA 24060	086134
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086132	QBiotics Group Ltd., suite 3A, level 1, 165 Moggill Rd., Taringa, Queensland 4068, Australia
086134	Revivicor, Inc., a wholly owned subsidiary of United Therapeutics Corp., 1700 Kraft Dr., suite 2400, Blacksburg, VA 24060
* * * * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. In § 520.292, revise paragraphs (a) and (c) to read as follows:

§ 520.292 Capromorelin**.**

(a) *Specifications*. Each milliliter of solution contains:

(1) 30 milligrams (mg) capromorelin; or

(2) 20 mg capromorelin.

* * * * *

(c) *Conditions of use*--(1) *Dogs*. Use product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. Administer 3 mg/kg once daily by mouth.

(ii) *Indications for use*. For appetite stimulation in dogs.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*. Use product described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Administer 2 mg/kg once daily by mouth.

(ii) *Indications for use*. For management of weight loss in cats with chronic kidney disease.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

5. In § 520.522, add paragraph (b)(3) to read as follows:

§ 520.522 Cyclosporine.

* * * * *

(b) * * *

(3) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1) of this section.

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

7. Add § 522.2450 to read as follows:

§ 522.2450 Tigilanol.

(a) *Specifications*. Each milliliter (mL) of solution contains 1 milligram tigilanol tiglate.

(b) *Sponsor*. See No. 086132 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*--(1) *Amount*. Administer as an intratumoral injection at a dose of 0.5 mL per cubic centimeter of tumor volume.

(2) *Indications for use*. For the treatment of non-metastatic cutaneous mast cell tumors and non-metastatic subcutaneous mast cell tumors located at or distal to the elbow or the hock in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

8. In § 522.2470, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) * * *

(1) Nos. 026637 and 054771 for use as in paragraph (c) of this section.

(2) No. 051311 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

* * * * *

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

9. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

10. In § 524.2098:

a. Revise paragraphs (a) and (b);

b. Remove paragraph (c) and redesignate paragraph (d) as paragraph (c); and

c. Revise newly redesignated paragraph (c)(1).

The revisions read as follows:

§ 524.2098 Selamectin.

(a) *Specifications.* Each milliliter contains 60 or 120 milligrams (mg) of selamectin.

(b) *Sponsors*. See Nos. 054771, 055529, 061133, and 061651 in § 510.600(c) of this chapter.

(c) * * *

(1) *Amount.* Administer topically 2.7 mg of selamectin per pound (6 mg per kilogram) of body weight.

* * * * *

PART 528--NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

11. The authority citation for part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

12 Add § 528.2001 to read as follows:

§ 528.2001 *pPL657* recombinant deoxyribonucleic acid construct.

(a) *Specifications*. *pPL657* in the *glycoprotein galactosyltransferase alpha-1,3* (*GGTA1*) gene in domestic pigs.

(b) *Sponsor*. See No. 086134 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Intended use*. *pPL657* rDNA construct in the *glycoprotein galactosyltransferase alpha-1,3* gene (*GGTA1*) in the lineage of domestic pigs (*Sus scrofa domesticus*) hemizygous and homozygous for the intentional genomic alteration resulting in undetectable endogenous galactose alpha-1,3-galactose sugar residues on biological derivatives of domestic pigs homozygous for the intentional genomic alteration lineage that are intended to be used as sources of food or human therapeutics including excipients, devices, drugs, or biological products.

(2) *Limitations*. Pigs of this lineage (possessing the intentional genomic alteration (*pPL657* rDNA construct)) should not be treated with aminoglycoside drugs and must only be housed in physically contained facilities specified in the approved application.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

13. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

14. In § 558.128, revise paragraph (e)(4)(xv) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(xv) 350 mg/head/day		1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline	Withdrawal periods: To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 hours prior to slaughter. To sponsor No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal period.	054771 066104 069254
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline	Withdrawal periods: To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048-761 and No. 069254 under NADA 138-935 and ANADA 200-510: Zero withdrawal period.	054771 066104 069254
* * * * * * *				

* * * * *

15. In § 558.342:

a. Revise paragraphs (d)(3) through (6); and

b. Remove paragraphs (d)(7) and (8).

The revisions read as follows:

§ 558.342 Melengestrol.

* * * * *

(d) * * *

(3) Liquid or dry combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be labeled in accordance with § 558.311(d).

(4) Liquid or dry combination Type B or C medicated feeds containing melengestrol acetate and monensin must be labeled in accordance with § 558.355(d).

(5) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(d).

(6) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

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Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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